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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,901	06/18/2001	Carol H. Miao	UOFW117396	1704

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EXAMINER
BURKHART, MICHAEL D

ART UNIT PAPER NUMBER
1633

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,901

Applicant(s)

MIAO ET AL.

Examiner

Michael D. Burkhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 March 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 15, 16, and 24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 16 and 24 is/are rejected.
- 7) Claim(s) 15 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
- Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Receipt and entry of the amendment dated 3/10/2006 is acknowledged. After entry of the amendment, claims 1-4, 15, 16, and 24 are pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new rejection necessitated by amendment of the claims. This is a New Matter rejection.

Amended claim 24 recites the expression cassette of claim 1, further comprising an enhancer sequence consisting of SEQ ID NO: 8, which is the human ApoE enhancer. Thus, the cassette of claim 1 must comprise either SEQ ID NO: 4 or 9, and SEQ ID NO: 8. The response indicates support for the amendment may be found at page 19, lines 18-20 and page 20, lines 4-16. These passages do not recite a cassette comprising SEQ ID NO: 4 or 9 in conjunction with SEQ ID NO: 8, but rather disclose the cassette may comprise SEQ ID NO: 4, 9, or 8. A reading of the remainder of the specification reveals no support for an expression cassette comprising both SEQ ID NO: 4 (or 9) and SEQ ID NO: 8. A review of the sequence search results reveals

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both SEQ ID NO: 4 and 9 comprise SEQ ID NO: 8. However, it is clear from the claim language that the cassette must "further comprise" SEQ ID NO: 8 in addition to SEQ ID NO: 4 or 9. There appears to be no support for this limitation and thus the amended claim includes impermissible New Matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection necessitated by amendment of the claims.**

Claims 2-4 recite the cassette of claim 1 wherein said cassette is "expressed in a transgenic animal or a recombinant AAV vector." It is unclear how the cassette can be expressed in a recombinant AAV vector, which is a viral vector existing in either an episomal plasmid-like state or as a virion. As such, it relies upon the host cell for transcription and translation factors necessary for gene expression. A reading of the specification indicates that the claimed cassette is disclosed as being a component of such an AAV vector, and it would be remedial to claim it as such.

Double Patenting

Applicant is advised that should claim 1 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a

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substantial duplicate of the allowed claim. See MPEP § 706.03(k). **This is a new rejection necessitated by amendment of the claims.**

Claim 1 recites an expression cassette comprising the human Factor IX cDNA sequence SEQ ID NO: 2. Thus, the cassette already encodes the Factor IX polypeptide set forth in SEQ ID NO: 3 and recited in claim 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al (U.S. Patent 6,936,243, effective filing date of 12/2/1996) as evidenced by Simonet et al (1993 and 1994) and Nguyen et al (Oncogene, 1996) in view of Jallat et al (EMBO Journal,

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1990) and Kurachi et al (J. Biol. Chem., 1995). This rejection is maintained for reasons made of record in the Office Action dated 12/12/2005 and for reasons outlined below.

Response to Arguments

Applicant's arguments filed 3/10/2006 have been fully considered but they are not persuasive. Applicants argue that the claimed expression cassette is unexpectedly effective at expressing Factor IX protein in liver cells, thus rebutting the rejection. Applicants also recite a passage from the specification indicating that a vector entitled LX-ApoE-HCR-hAAT-FIXmg-bpA as an example of such expression efficiency. This argument is not found persuasive for two reasons: 1) the LX-ApoE-HCR-hAAT-FIXmg-bpA vector does not comprise the cassette as claimed because it comprises the Factor IX 3' untranslated region (recited in claim 15 as SEQ ID NO: 7); and, 2) it would not be unexpected to observe an increase of expression upon use of the Factor IX intron in the claimed cassette, as such an increase is taught by Jallat et al and Kurachi et al (see the USC §103 rejection in the Office Action dated 12/12/2005). The claimed nucleic acid expression cassettes are essentially disclosed in the recombinant AAV vectors of Snyder et al with the exception of the inclusion of an intron. Because Jallat and Kurachi et al both teach an increase of expression upon use of the Factor IX intron in such a cassette, the skilled artisan would therefore expect an increase of Factor IX expression.

Conclusion

Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach the use of SEQ ID NO: 7, but rather a

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highly related sequence (e.g. SEQ ID NO: 4 from U.S. Patent 6,610,906) differing from SEQ ID NO: 7 by only two nucleotides. There is no evidence of record suggesting changing the prior art sequence to that of SEQ ID NO: 7.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

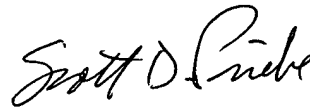
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
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SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER